

Attorney Docket No.: 6196.210-US
USSN: 10/667,040
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IN THE CLAIMS:

1-4 (Cancelled)

5. (Previously Presented) An injection device for injecting a dose of medication from a cartridge having a moveable piston at one end and a pierceable membrane at an opposite end, the device comprising:

- a. a distal end from which medication can be expelled;
- b. an axially displaceable element that moves in a proximal direction during dose setting and that receives a force from user that is directed in a distal direction during injection;
- c. a piston drive element for engaging and moving a piston within a medication cartridge in a distal direction to expel medication from the cartridge;

a gearing coupling the axially displaceable element with the piston drive element, the gearing increasing the force exerted by the user on the axially displaceable element so that a greater force is exerted on the piston drive element, the gearing comprising a first rack that is connected to the axially displaceable element, the first rack being in continuous meshed engagement with a pinion during dose setting and injection of a dose, wherein the gearing causes the piston drive element to move a distance in a distal direction during injection that is less than the distance moved by the first rack.

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6. (Previously Presented) The device of claim 5, wherein the gearing causes the piston drive to move half the distance that the axially displaceable element moves during injection of a dose.
7. (Previously Presented) An injection device for injecting a dose of medication from a cartridge having a moveable piston at one end and a pierceable membrane at an opposite end, the device comprising:
 - a. an axially displaceable element that moves in a first direction during dose setting and that receives a force from user that is directed in an opposite, second direction during injection;
 - b. a piston drive element for engaging and moving a piston within a medication cartridge in the second direction to expel medication from the cartridge during injection
 - c. a transmission assembly coupling the axially displaceable element with the piston drive element, the transmission assembly comprising:
 - i. a first rack that moves axially in the first and second direction with the axially displaceable element;
 - ii. a pinion in continuous meshed engagement with the rack during motion of the rack in both the first and second directions;
 - iii. a second pinion that rotates in unison with the first pinion during injection of a dose;
 - iv. a transmission output connection member that connects at least the second pinion and the piston drive and that drives the piston drive to move a distance less than the distance the first rack moves.

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8. (Previously Presented) An injection device for injecting a dose of medication from a cartridge having a moveable piston at one end and a pierceable membrane at an opposite end, the device comprising:
- a. an axially displaceable element that moves in a proximal direction during dose setting and that receives a force from user that is directed in a distal direction during injection;
 - b. a piston drive element for engaging and moving a piston within a medication cartridge in a distal direction to expel medication from the cartridge;
 - c. a rack and pinion assembly connecting the axially displaceable element to the piston drive element, the rack and pinion assembly comprising:
 - i. a first rack that moves distally and proximally with the axially displaceable element
 - ii. a first pinion in continuous meshed engagement with the first rack during both dose setting and injection
 - iii. a second rack that is in continuous meshed engagement with a second pinion; and
 - iv. wherein the gearing in the rack and pinion assembly causes the piston drive to move a shorter distance than the axially displaceable element during injection thereby resulting in an increased force on the piston drive as compared to the force exerted on the axially displaceable member.
9. (Previously Presented) An injection device comprising:

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- a. An injection button that moves forward during injection and backward during setting of a dose to be injected
- b. A piston drive for moving a piston within a medication cartridge to expel medication from the cartridge;
- c. A transmission that transmits force from the injection button, to the piston drive, one portion of the transmission physically connected to the injection button and an other portion of the transmission physically connected to the piston drive, the transmission further comprising:
 - i. A first rack that moves forward and backwards with the injection button;
 - ii. A first pinion in continuous meshed engagement with the first rack during both backward and forward motion;

A second rack in continuous meshed engagement with a second pinion, and wherein the first and second pinions have different diameters and wherein they rotate during injection at the same rotational speed thereby creating a mechanical advantage that results in the transmission driving the piston drive a distance that is less than the distance a user drives the injection button during injection of a dose of medication.

10. (Previously Presented) A method for expelling medication from an injection device having a rack and pinion transmission that couples an injection button with a piston driver; the method comprising the steps of:

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- a. moving a first rack rearward during setting of a dose, the rack remaining in continuous meshed engagement with a pinion causing that to rotate during setting of the dose;
 - b. moving the first rack forward during injection of a dose and causing the pinion to rotate in an opposite direction, thereby causing part of the transmission to drive the piston driver forward which in turn moves a piston within a medication cartridge and expels medication from the device.
11. (Previously Presented) The method of claim 10, further comprising the step of:
- a. Rotating a second smaller pinion at the same speed as the pinion of claim 10 during the expelling of the medication,
 - b. Wherein the second pinion is in continuous meshed engagement with a second rack.
12. (Previously Presented) The method of claim 10, wherein the first rack moves forward by a distance greater than the piston is drive forward during injection.
13. (New) A drug delivery device comprising:
- a piston rod having at least one threaded portion (4);
 - a dose dial sleeve (17) threadedly engaged with a portion of the device and having a scale indicative of dose sizes and wherein the dose dial sleeve is rotatable during a dose setting operation so that it can be rotated to a position where a predetermined dose is indicated on the scale;
 - a drive sleeve (20); and

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a clutch (21), which is comprised of one or more components (33, 32), that releasably couples the dose dial sleeve (17) and the drive sleeve (20); and wherein:

(i) during the dose setting operation the dose dial sleeve (17) and the drive sleeve (20) are coupled by the clutch so that they rotate together; and

(ii) during injecting of medication from the device, the dose dial sleeve (17) is decoupled from the drive sleeve (20) and so that it rotates back to an original pre-dose setting position upon completion of the injection but the drive sleeve (20) does not rotate during injecting of medication but instead moves in a longitudinal direction toward an injecting end of the device.

14. (New) The device of claim 13, wherein the drive sleeve is coupled to a gear box that is in turn coupled to the threaded piston rod so that portion of the longitudinal force exerted by the user that is transmitted to the piston rod is transmitted thru both the drive sleeve and the gear box and wherein the gear box multiplies the force.

15. (New) The device of claim 13, wherein a longitudinal force exerted by a user in a direction toward the injecting end of the device is transmitted thru the drive sleeve to the piston rod; and

wherein the longitudinal force also acts upon the dose dial sleeve and, as a result of this longitudinal force and longitudinal movement of the drive sleeve, the dose dial sleeve rotates during injecting of medication from the device even

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though the dose dial sleeve is rotationally decoupled from the drive sleeve during
injecting.